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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,387

01/05/2006

David Peter Shaw

PL10-002

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

06/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,387	<b>Applicant(s)</b> SHAW, DAVID PETER	
	<b>Examiner</b> ANN SCHILLINGER	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11,14 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11,14 and 23-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3774

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 10 state that the flap valve consists only of a flexible openwork structure that allows movement of liquid through the valve in only one direction. It is unclear how the *openwork*, knitted structure of the valve will be able to control the movement of the liquid without any other structural features to prevent the fluid from moving through openings of the valve.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

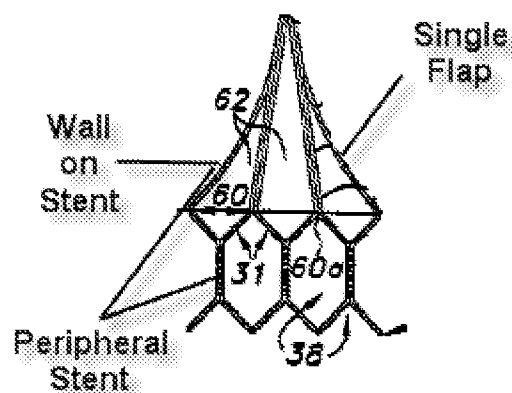
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-34 are rejected under 35 U.S.C. 102(e) as being anticipated by DiMatteo et al. (US Pat. No. 7,267,686). DiMatteo et al. discloses the following of claim 23: a prosthetic valve

Art Unit: 3774

comprising: a flap valve (10) that includes at least one flap (40) arranged to allow movement of liquid through the prosthetic valve only in one direction; the at least one flap consisting of a flexible openwork structure of a medically acceptable metal coated with a degradable sealing material (80; col. 3, lines 4-22), the degradable sealing material being configured as an initial coating to prevent leakage through the flexible openwork structure until such time as a living subject develops a coating over the at least one flap by endothelialisation; and the flexible openwork structure being selected from the group consisting of: knitted wire and chainmail (col. 4, lines 33-44; Figs. 1-8).

DiMatteo et al. discloses claim 24 as shown in the following figure:



DiMatteo et al. discloses the following of claim 25: the prosthetic valve as claimed in claim 23 wherein said valve includes two flaps (40) arranged to close against each other.

DiMatteo et al. discloses the following of claim 26: the prosthetic valve as claimed in claim 25 wherein said valve further includes a peripheral stent (30) supporting a wall (31)

Art Unit: 3774

extending at right angles to the plane of the stent and providing two opposed cutouts (62) in which said flaps are mounted.

DiMatteo et al. discloses the following of claim 27: the prosthetic valve as claimed in claim 23 wherein said valve includes three flaps (40) of similar size, arranged to close against each other (Figs. 1-8).

DiMatteo et al. discloses the following of claim 28: the prosthetic valve as claimed in claim 27 wherein said valve also includes a peripheral rib (31).

DiMatteo et al. discloses the following of claim 29: the prosthetic valve as claimed in claim 27 wherein said valve further includes a peripheral stent (30) upon which the three flaps are mounted.

DiMatteo et al. discloses the following of claim 30: the prosthetic valve as claimed in claim 23 wherein the medically acceptable metal is titanium or a titanium alloy (col. 4, lines 33-44).

DiMatteo et al. discloses the following of claim 31: the prosthetic valve as claimed in claim 23 wherein the prosthetic valve is a heart valve (col. 1, lines 16-18).

DiMatteo et al. discloses the following of claim 32: a method of promoting tissue growth and endothelialisation, minimizing the risk of foreign body infection following the fitting of a prosthetic valve in a living subject, said method comprising: providing a prosthetic valve including: a flap valve (10) that includes at least one flap (40) arranged to allow movement of liquid through the prosthetic valve only in one direction; the at least one flap consisting of a flexible open work structure of a medically acceptable metal (col. 4, lines 33-44) coated with a degradable sealing material (80; col. 3, lines 4-22), the degradable sealing material being

Art Unit: 3774

configured as an initial coating to prevent leakage through the flexible open work structure until such time as a living subject develops a coating (80) over the at least one flap by endothelialisation; and the flexible open work structure being selected from the group consisting of: knitted wire and chainmail (Figs. 1-8).

DiMatteo et al. discloses the following of claim 33: the method as claimed in claim 32 wherein the prosthetic valve is a heart valve (col. 1, lines 16-18).

DiMatteo et al. discloses the following of claim 34: the method as claimed in claim 32 wherein the medically acceptable metal is titanium or a titanium alloy (col. 4, lines 33-44).

### ***Response to Arguments***

Regarding claims 1-7, 9-11, and 14 are have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 3/17/2010 regarding claims 23-34 have been fully considered but they are not persuasive. The Applicant contends that the DiMatteo reference does not disclose valve flaps consisting of metal framework and a degradable cover. The examiner respectfully disagrees. The DiMatteo reference discloses a metal openwork structure with a liner that serves as a covering (abstract). DiMatteo also states that the entire structure may be made of a bioabsorbable material (col. 3, lines 4-22).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 3774

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN SCHILLINGER whose telephone number is (571)272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571) 272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./

Application/Control Number: 10/563,387

Page 7

Art Unit: 3774

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774